REMARKS

Applicants respectfully request entry of this Amendment and reconsideration of this application in view of the above amendments and following remarks.

Claims 1 -9 and 13 – 26 are cancelled without prejudice to the prosecution of the subject matter in this or related applications.

Claims 10 – 12 are currently pending.

Independent claim 10 has been amended to recite a method for inducing an immune response by administering smooth spherical, colloidal calcium phosphate core particles with a surface modifying agent at least partially coating the particles, and having an allergen at least partially coating the surface modifying agent. Support for the amendment can be found in the specification at, for example: page 5, lines 4-9; page 7, lines 1-3; page 8, line 26-page 9, line 8; and also in the original claims as filed.

Claim Rejections Under 35 U.S.C. § 102 (b)

Claims 10 – 12 were rejected under 35 U.S.C. § 102 (b) as being anticipated by Lee et al. (WO 00/15194). As amended, the claims recite a method for inducing an immune response by administering smooth spherical, colloidal calcium phosphate core particles with a surface modifying agent at least partially coating the particles, and having an allergen at least partially coating the surface modifying agent. Because Lee does not disclose a method of inducing an immune response using smooth spherical, colloidal calcium phosphate particles at least partially coated with a surface modifying agent that adheres an allergen to the calcium phosphate particles, applicants respectfully traverse the rejection.

The claimed method involves using surface modifying agents which act as a biological "glue" to bind an allergen to smooth calcium phosphate particles. (*See, e.g.*, specification at page 5, ll. 5-8; page 6, ll. 1-3; and page 8, ll. 26-page 9, ll. 8.) The use of a surface modifying agent facilitates the binding of the allergen to the smooth calcium phosphate particles and thereby increases the adjuvanticity of the particles without otherwise decreasing the biocompatibility of the formulation.

WO 00/15194 to Lee et al. ("Lee"), in contrast, does not disclose, teach or suggest inducing an immune response using smooth spherical, colloidal calcium phosphate particles coated with a surface modifying agent to adhere an allergen to the calcium phosphate particles. Specifically, Lee discloses using calcium phosphate particles of various size and

shape, including spherical, platelet-like, amorphous, and needle-like shapes, as adjuvants to increase an immune response. (Lee at page 15, ll. 22-28.) Lee further discloses that adjuvanticity can be increased by increasing the surface area of the particles (Lee at page 16, ll. 17-18) or by "modify[ing] the surface of the calcium adjuvant in order to improve the interface between the adjuvant and the active agent." (*Id.* at page 27, ll. 26-28.) However, while roughening the particle surface may increase the total surface area and may improve the binding of an active agent to the calcium phosphate core particles, Lee points out that "the degree of surface roughness is known to have specific effects on biocompatibility, with extreme surface roughness being associated with decreased biocompatibility." (*Id.* at page 16, ll. 5-7.)

The claimed method provides both the desired adjuvanticity and biocompatibility in a manner not contemplated by Lee, namely by using smooth spherical, colloidal calcium phosphate particles along with a surface modifying agent which acts as a biological "glue" to bind an allergen to the smooth calcium phosphate particles. The claimed method of inducing a therapeutic immune response using a surface modifying agent increases adjuvanticity without roughening the surface of the calcium phosphate particles. The method thus provides increased adjuvanticity without negatively affecting the biocompatibility of the adjuvant. Lee does not disclose a method for inducing an immune response by administering smooth calcium phosphate core particles with a surface modifying agent at least partially coating the particles, and having an allergen at least partially coating the surface modifying agent, and thus does not disclose all of the elements of claims 10, 11 or 12. Lee therefore does not anticipate the claims. Applicants thus request that the rejection of all pending claims 10 – 12 be withdrawn.

Conclusion

Allowance of the pending claims is respectfully requested. The Examiner is encouraged to contact the undersigned attorney regarding any matter concerning this application.

Respectfully submitted,
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